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May 20, 1999

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Assistant Commissioner for Patents  
Washington, D.C. 20231

MAY 21 1999  
MATRIX CUSTOMER  
SERVICE CENTER

Re: U.S. Utility Patent Application  
Appl. No. 09/245,025; Filed: February 5, 1999  
For: Compositions and Methods for Reverse Transcription of Nucleic Acid  
Molecules  
Inventors: GERARD *et al.*  
Our Ref: 0942.4330003/RWE/BJD

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement (*in duplicate*);
2. Form PTO-1449 (20 pages); and
3. One return post card

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

**STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.**

Assistant Commissioner for Patents  
May 20, 1999  
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036. A duplicate copy of this letter is enclosed.

Respectfully submitted,

**STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.**



Brian J. Del Buono  
Agent for Applicants  
Registration No. 42,473

RWE/BJD/dmb  
Enclosures

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

GERARD *et al.*

Appl. No. 09/245,025

Filed: February 5, 1999

For: **Compositions and Methods for  
Reverse Transcription of Nucleic  
Acid Molecules**



Art Unit: 1643

Examiner: To be assigned

Atty. Docket: 0942.4330003/RWE/BJD

**Information Disclosure Statement**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of the cited documents were provided to the Office in Application No. 09/064,057, filed April 22, 1998, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached hereto. 37 C.F.R. § 1.98(d).

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

The Examiner's attention is directed to the following commonly owned, co-pending U.S. applications, which concern related technical subject matter:

<u>Application No.</u>	<u>Filing Date</u>	<u>Docket No.</u>
08/798,458	February 10, 1997	0942.0490007
09/054,485	April 3, 1998	0942.4370001
09/076,115	May 12, 1998	0947.4350001
09/220,329	December 24, 1998	0942.0490009
09/220,330	December 24, 1998	0942.0490008

The identification of these U.S. Patent Applications is not to be construed as a waiver of secrecy as to the applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination of the present application.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

This Information Disclosure Statements is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Brian J. Del Buono  
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Date: May 20, 1999

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SKGF Rev. 1/26/98 clp

FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u> <i>1449-23 1999</i>		ATTY. DOCKET NO. 0942.4330003	APPLICATION NO. 09/245,025
		APPLICANT GERARD, et al.	
		FILING DATE February 5, 1999	GROUP <i>1643 1652</i>

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
AA1	4,663,290	05/05/1987	Weis et al.	435	253	01/21/1982
AB1	4,889,818	12/26/1989	Gelfand et al.	435	194	06/17/1987
AC1	4,965,188	10/23/1990	Mullis et al.	435	6	06/17/1987
AD1	5,244,797	09/14/1993	Kotewicz et al.	435	194	03/18/1991
AE1	5,310,652	05/10/1994	Gelfand et al.	435	6	06/24/1993
<i>me</i> AF1	5,322,770	06/21/1994	Gelfand, D.H.	435	6	12/22/1989
AG1	5,374,553	12/20/1994	Gelfand et al.	435	252.3	08/13/1990
AH1	5,405,776	04/11/1995	Kotewicz et al.	435	252.33	01/24/1992
<i>me</i> AI1	5,407,800	04/18/1995	Gelfand et al.	435	6	06/17/1993
AJ1	5,436,149	07/25/1995	Barnes, W.M.	435	194	02/19/1993
AK1	5,512,462	04/30/1996	Cheng, S.	435	91.2	02/25/1994

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
AL1	WO 92/06188	04/16/1992	WIPO	—	—	Yes No
AM1	WO 92/06200	04/16/1992	WIPO	—	—	Yes No
AN1	WO 96/10640	04/11/1996	WIPO	—	—	Yes No
AO1	WO 97/24455	07/10/1997	WIPO	—	—	Yes No
AP1	EP 0 791 650 A1	08/27/1997	Europe	—	—	Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	1	Aatinski, J.T., et al., "A Coupled One-Step Reverse Transcription PCR Procedure For Generation of Full-Length Open Reading Frames," <i>BioTechniques</i> 16:282-288 (1994).
AS	1	Abbotts, J., et al., "Mechanism of HIV-1 Reverse Transcriptase," <i>J. Biol. Chem.</i> 268:10312-10323 (May 1993).
<i>me</i> AT	1	Alexander, F., et al., "Proteolytic Processing of Avian Sarcoma and Leukosis Viruses pol-endo Recombinant Proteins Reveals Another pol Gene Domain," <i>J. Virol.</i> 61:534-542 (February 1987).

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.	

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EXAMINER INITIAL	DOCUMENT NUMBER	DATE	OFFICE NAME	CLASS	SUB-CLASS	FILING DATE
AA2	5,556,771	09/17/1996	Shen et al.	435	91.2	02/10/1995
AB2	5,561,058	10/01/1996	Gelfand, et al.	435	912	5/24/1995
AC2	5,618,702	04/08/1997	Scanlon, K.J.	435	91.2	08/06/1993
AD2	5,618,703	04/08/1997	Gelfand et al.	435	91.2	02/22/1994
AE2	5,618,711	04/08/1997	Gelfand et al.	435	194	02/06/1995
AF2	5,624,833	04/29/1997	Gelfand et al.	435	194	06/07/1995
AG2	5,641,864	06/24/1997	Gelfand, D.H.	530	350	09/22/1994
AH2	5,668,005	09/16/1997	Kotewicz et al.	435	194	03/12/1996
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## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
AL2	WO 98/51789	11/19/1998	WIPO			Yes No
AM						Yes No
AN						Yes No
AO						Yes No
AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	2	Anderson, D., et al., "Rapid Generation of Recombinant Baculovirus and Expression of Foreign Genes Using the BAC-TO-BAC™ Baculovirus Expression System," FOCUS 17:53-58 (1995).
AS	2	Barnes, W.M., "The fidelity of Taq polymerase catalyzing PCR is improved by an N-terminal deletion," Gene 112:29-35 (1992).
AT	2	Barr, P.J., et al., "Expression of Active Human Immunodeficiency Virus Reverse Transcriptase in <i>Saccharomyces cerevisiae</i> ," BioTechnology 5:486-489 (May 1987).

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EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
AL						Yes No
AM						Yes No
AN						Yes No
AO						Yes No
AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	3	Berger, S.L., et al., "Reverse Transcriptase and Its Associated Ribonuclease H: Interplay Two Enzyme Activities Controls the Yield of Single-Stranded Complementary Deoxyribonucleic Acid," <i>Biochemistry</i> 22:2365-2372 (1983).
AS	3	Chattopadhyay, D., et al., "Purification and Characterization of Heterodimeric Human Immunodeficiency Virus Type 1 (HIV-1) Reverse Transcriptase Produced by <i>in Vitro</i> Processing of p66 with Recombinant HIV-1 Protease," <i>J. Biol. Chem.</i> 267:14227-14232 (July 1992).
AT	3	Chernov, A.P., et al., "Recombinant Reverse Transcriptase of Rous Sarcoma Virus: Characterization of DNA Polymerase and RNAase H activities," <i>Biomed. Sci.</i> 2:49-53 (1991).

EXAMINER	DATE CONSIDERED

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FORM PTO-1449		O I P T MAY 20 1999 PATENT & TRADEMARK OFFICE		ATTY. DOCKET NO. 0942.4330003	APPLICATION NO. 09/245,025
INFORMATION DISCLOSURE STATEMENT				SAPPLICANT GERARD, et al.	
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## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

<i>we</i>	AR	4	Dudding, L.R., et al., "Analysis of the RNA- and DNA-Dependent DNA Polymerase Activities of Point Mutants of HIV-1 Reverse Transcriptase Lacking Ribonuclease H Activity," <i>Biochemistry</i> 30:10498-10506 (1991)
	AS	4	Freeman, W.M., et al., "Use of Elevated Reverse Transcription Reaction Temperature in RT-PCR," <i>BioTechniques</i> 20:782-783 (May 1996).
	AT	4	Flaman, J.M., et al., "A Rapid PCR Fidelity Assay," <i>Nucleic Acids Res.</i> 22:3259-3260 (August 1994).

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	5	Gerard, G.F., et al.. "Poly(2'-O-methylcytidylate) Oligodeoxyguanylate as a Template for the Ribonucleic Acid Directed Deoxyribonucleic Acid Polymerase in Ribonucleic Acid Tumor Virus Particles and a Specific Probe for the Ribonucleic Acid Directed Enzyme in Transformed Murine Cells," <i>Biochemistry</i> 13:1632-1641 (April 1974).
	AS	5	Gerard, G.F., et al.. "cDNA Synthesis by Clone Moloney Murine Leukemia Virus Reverse Transcriptase Lacking RNase H Activity," <i>FOCUS</i> 11:66-69 (1989).
	AT	5	Gerard, G.F. et al., "cDNA Synthesis by Moloney Murine Leukemia Virus RNase H-Minus Reverse Transcriptase Possessing Full DNA Polymerase Activity," <i>FOCUS</i> 14:91-93 (1992).

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		FILING DATE February 5, 1990	GROUP 1643

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	AL						Yes No
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	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	6	Gerard, G.F., "Reverse Transcriptase: A Historical Perspective," FOCUS 20(3):65-67 (Fall 1998).
	AS	6	Grandgenett, D.P., et al., "A Single Subunit from Avian Myeloblastosis Virus with Both RNA-Directed DNA Polymerase and Ribonuclease H Activity," Proc. Natl. Acad. Sci. USA 70:230-234 (January 1973).
	AT	6	Grandgenett, D.P., et al., "Large-Scale Purification of Ribonucleic Acid Tumor Viruses by Use of Continuous-Flow Density Gradient Centrifugation," Appl. Microbiol. 26:452-454 (September 1973).

EXAMINER	DATE CONSIDERED
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FORM PTO-1449  INFORMATION DISCLOSURE STATEMENT		ATTY. DOCKET NO. <i>NO MAY 20 1999</i> 0942.4330003, <i>JC63</i>	APPLICATION NO. 09/245,025
		APPLICANT GERARD, et al.	
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	AL						Yes No
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	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	7	Gubler, U., and Hoffman, B.J., "A Simple and Very Efficient Method for Generating cDNA Libraries," <i>Gene</i> 25:263-26 (November 1983).
	AS	7	Hizi, A., and Joklik, W.K., et al., "RNA-dependent DNA Polymerase of Avian Sarcoma Virus B77," <i>J. Biol. Chem.</i> 252:2281-2289 (April 1977)..
<i>me</i>	AT	7	Hizi, A., et al., "Mutational Analysis of the Ribonuclease H Activity of Human Immunodeficiency Virus 1 Reverse Transcriptase," <i>Virology</i> 175:575-580 (1990).

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FORM PTO-1449 <b>INFORMATION DISCLOSURE STATEMENT</b>		ATTY. DOCKET NO. 0942.4330003	APPLICATION NO. 09/245,025
		APPLICANT GERARD, et al.	<i>O I P</i> <i>MAY 20 1990</i> <i>J.C. G.</i> <i>PATENT &amp; TRADEMARK OFFICE</i>
		FILING DATE February 5, 1990	
		GROUP 1643	

## U.S. PATENT DOCUMENTS

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>8</u>	Hostomsky, Z., et al., "Reverse Transcriptase of Human Immunodeficiency Virus Type 1:Functionality of Subunits of the Heterodimer in DNA Synthesis," <i>J. Virol.</i> 66:3179:3182 (May 1992).
AS	<u>8</u>	Houts, G.E., et al., "Reverse Transcriptase from Avian Myeloblastosis Virus," <i>J. Virol.</i> 29:517-522 (February 1979).
AT	<u>8</u>	Huber, H.E., et al., "Human Immunodeficiency Virus 1 Reverse Transcriptase," <i>J. Biol. Chem.</i> 264:4469-4678 (March 1989).

EXAMINER

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	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

<i>ME</i>	AR	9	Johnson, M.S., et al., "Computer analysis of retroviral pol genes: Assignment of enzymatic functions to specific sequences and homologies with nonviral enzymes," Proc. Natl. Acad. Sci. USA 83:7648-7652 (October 1986).
<i>ME</i>	AS	9	Kanaya, S., et al., "Identification of the Amino Acid Residues Involved in an Active Site of Escherichia coli Ribonuclease H by Site-directed Mutagenesis," J. Biol. Chem. 265:4615-4621.
	AT	9	Kawa, S., et al., "Expression and Purification of the HIV-1 Reverse Transcriptase Using the Baculovirus Expression Vector System," Prot. Exp. Purif. 4:298-303 (August 1993).

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	10	Knapp, B., et al.. "In vitro translation of <i>Plasmodium falciparum</i> aldolase is not initiated at an unusual site," <i>EMBO J.</i> 10:3095-3097 (October 1991).
	AS	10	Kokko, H.I., et al., "Single-Step Immunocapture RT-PCR in the Detection of Raspberry Bushy Dwarf Virus," <i>BioTechniques</i> 20:842-846 (May 1996).
	AT	10	Kotewicz, M.L., et al.. "Isolation of Cloned Maloney Murine Leukemia Virus Reverse Transcriptase Lacking Ribonuclease H Activity," <i>Nucl. Acids Res.</i> 16:265-277 (1988).

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	AR	11	Krug, M.S., et al.. "First-Strand cDNA Synthesis Primed with Oligo(dT)," <i>Meth. Enzymol.</i> 152:316-325 (1987).
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FORM PTO-1449  <u>INFORMATION DISCLOSURE STATEMENT</u>		ATTY. DOCKET NO. 0942.4330003	PATENT & TRADEMARK OFFICE O I P MAY 20 1999 C.C.	APPLICATION NO. 09/245,025
		APPLICANT GERARD, et al.		
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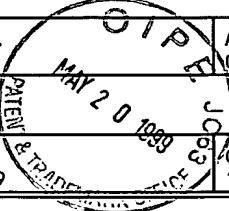
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AR	<u>12</u>	Le Grice, S.F.J., and Grüninger-Leitch, F., "Rapid Purification of Homodimer and Heterodimer HIV-1 Reverse Transcriptase by Metal Chelate Affinity Chromatography," <i>Eur. J. Biochem.</i> 187:307-314 (January 1990).
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AT	<u>12</u>	Lowe, D.M., et al., "HIV-1 Reverse Transcriptase: Crystallization and Analysis of Domain Structure by Limited Proteolysis," <i>Biochemistry</i> 27:8884-8889 (December 1988).

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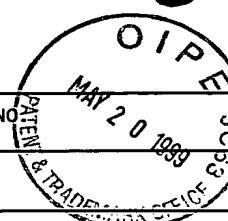
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AT	<u>16</u>	Sellner, L.N., et al., "Reverse transcriptase inhibits Taq Polymerase Activity," <i>Nucl. Acids Res.</i> 20:1487-1490 (1992).

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	AR	17	Sitaraman, K., et al.. "RT-PCR of Difficult Templates Using the Superscript One-Step™ RT-PCR System," <i>FOCUS</i> 19:43-44 (Spring 1997).
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	AS	<u>18</u>	Strauss, E.M., et al.. "Efficient Production of Mammalian RNA Tumor Viruses in Serum-Free Culture Medium Allows Rapid RNA Subunit Purification," <i>J. Virol. Meth.</i> 1:213-221 (1980).
	AT	<u>18</u>	Telesnitsky, A., and Goff, S.P., "RNase H domain mutations affect the interaction between Moloney murine leukemia virus reverse transcriptase and its primer-template," <i>Proc. Natl. Acad. Sci. USA</i> 90:1276-1280 (February 1993).

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	AR	19	Wang, R.F., et al.. "A Simplified, Single Tube, Single Buffer System for RNA-PCR," <i>BioTechniques</i> 12:702,704 (May 1992).
	AS	19	Weaver, D.T., and DePamphilis, M.L., "Specific Sequences in Native DNA that Arrest Synthesis by DNA Polymerase $\alpha$ ," <i>J. Biol. Chem.</i> 257:2075-2086 (February 1982).
<i>Ne</i>	AT	19	Boehringer Mannheim Biochemicals, "Reverse Transcriptase AMV," "Reverse Transcriptase M-MuLV," "Reverse Transcriptase, HIV-1," Products Catalogue, pp.92-93, (1995).

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	AS	<u>20</u>	Toyobo, Tokyo, Japan, "M-MLV Reverse Transcriptase (Rnase H-) ReverTraAce," Product Literature (1998).
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